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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,647	04/18/2001	William Ernest Alborn, JR.	X-13168	9595
25885	7590	11/18/2005	EXAMINER	
ELI LILLY AND COMPANY			LEWIS, PATRICK T	
PATENT DIVISION				
P.O. BOX 6288			ART UNIT	PAPER NUMBER
INDIANAPOLIS, IN 46206-6288			1623	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/833,647	ALBORN, ET AL.	
	<b>Examiner</b> Patrick T. Lewis	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 December 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-11,13-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 11 and 25 is/are allowed.
- 6) Claim(s) 2-6,13-21 and 27 is/are rejected.
- 7) Claim(s) 7-10 and 22-24 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 April 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

***Applicant's Response Dated December 10, 2003***

1. Claims 2-11, 13-25 and 27 are pending. An action on the merits of claims 2-11, 13-25 and 27 is contained herein below.
2. The rejection of claims 13-24 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment dated December 10, 2003.
3. The rejection of claims 25-27 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicant's arguments dated December 10, 2003.
4. The rejection of claims 7-10, 12 and 26 under 35 U.S.C. 103(a) as being unpatentable over Heijenoort et al. *J. Bacteriol.* 1992, Vol. 174, pages 3549-3557 (Heijenoort) has been rendered moot in view of applicant's amendment/arguments dated December 10, 2003.
5. The rejection of claims 2-6 under 35 U.S.C. 103(a) as being unpatentable over Heijenoort et al. *J. Bacteriol.* 1992, Vol. 174, pages 3549-3557 (Heijenoort) is maintained for the reasons of record as set forth in the Office Action dated May 6, 2003.

***Rejections of Record Set Forth in the Office Action Dated May 6, 2003***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heijenoort et al. *J. Bacteriol.* 1992, Vol. 174, pages 3549-3557 (Heijenoort).

Applicant's arguments filed May 6, 2003 have been fully considered but they are not persuasive. Applicant argues that since the levels of purity according to the present invention are not enabled by the prior art methods, they cannot be obvious. Applicant also contends that the product described in the prior art was not suited for the utility of the claimed product.

The examiner disagrees with applicant's assessment of the prior art and the instant rejection. Applicant is directed to column 2 of page 3553 wherein Heijenoort teaches the ratio of lipid I to lipid II as being 1:6 (86%) as determined by HPLC analysis. The purity level of lipid II as taught by Heijenoort renders the instant lipid II compositions obvious.

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim describes variables not shown in formula 1. The ambiguity of the claim renders it indefinite, as one of ordinary skill in the art would not be apprised of the metes and bounds of the invention.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 13-21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heijenoort et al. *J. Bacteriol.* 1992, Vol. 174, pages 3549-3557 (Heijenoort).

Claims 13-21 are drawn to a process for preparing purified lipid II comprising chromatographically separating lipid II analyte from a sample matrix utilizing a mobile phase maintained at a pH greater than 6 and collecting said analyte to provide said purified lipid II. Claim 27 is drawn to lipid II analog of formula 1.

Heijenoort teaches the purification of lipid II (column 2, pages 3550). Lipid II was purified via column chromatography using a methanol/ammonium acetate elution solvent. The elution was run first with 250 mL of methanol, with 40 mL of 0.4 M ammonium acetate in methanol, and thereafter with a linear gradient from 0.4 to 4 M ammonium acetate in methanol. The fractions containing radioactive lipid II were

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pooled and strongly mixed with 2 volumes of water and 2 volumes of 1-butanol saturated with water. After one night, the organic phase was recovered. The aqueous phase was submitted twice to the same extraction procedure. The three butanol extracts were pooled and evaporated to dryness under vacuum. The residue was dissolved in chloroform-methanol and subjected to additional column chromatography. The fractions containing radioactive lipid II were pooled and kept at -25 °C. The ratio of lipid I to lipid II was estimated at 1:6 (page 3553).

Heijenoort differs from the instantly claimed invention in that Heijenoort is silent on the extent of the purity of the lipid II. Although Heijenoort does not explicitly teach that lipid II is 90% pure, changing the form, purity or other characteristics of an old product does not render the novel form patentable where the difference in form, purity or characteristic was rendered obvious by the prior art. When claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material. Since no new properties and/or utilities have been set forth, the instantly claimed lipid II is indeed *prima facie* obvious.

### ***Conclusion***

13. Claims 2-11, 13-25 and 27 are pending. Claims 2-6, 13-21 and 27 are rejected. Claims 7-10 and 22-24 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 11 and 25 are allowed.

**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



\_\_\_\_\_  
Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623

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